DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2014

Arthrex, Incorporated
Mr. David L. Rodgers
Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

Re: K140855
Trade/Device Name: Arthrex SutureTak Suture Anchors
Regulation Number: 21 CFR 888.3080
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: November 17, 2014
Received: November 19, 2014

Dear Mr. Rodgers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.4 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140855

Device Name

Arthrex SutureTak Suture Anchors

Indications for Use *(Describe)*

The **Arthrex SutureTak Suture Anchors** are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clabicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hip: Capsular repair, Acetabular Labral repair

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FORM FDA 3881 (9/13)

PSC Publishing Services (301) 443-6740 EF

1.1 510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	December 12, 2014
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@arthrex.com
Trade Name	***Arthrex SutureTak Suture Anchors***
Common Name	Suture Anchor
Product Code, Classification Name, CFR	MAI, MBI 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Predicate Device	*K112237: Arthrex MicroSuture Anchors* *K110660: Arthrex BioComposite SutureTak* *K091844: Arthrex Bio-Composite SutureTak Suture Anchors* *K061863: Arthrex Corkscrew, Corkscrew FT, Bio-Corkscrew, and Bio Corkscrew FT Suture Anchors*
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the ***Arthrex SutureTak Suture Anchors*** for indications in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.
Device Description	The ***Arthrex SutureTak Suture Anchors*** share the same design features, materials, and intended use as the predicates. The anchors are composed of Polyetheretherketone (PEEK), or PLDLA/βTCP and are preloaded on a driver with nonabsorbable suture. The anchors range from 2.0mm – 3.0mm in diameter and 4.9mm – 14.5mm in length.
Intended Use	The **Arthrex SutureTak suture anchors** are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. **Shoulder**: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clabicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis **Hand/Wrist**: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction **Hip**: Capsular repair, Acetabular Labral repair

Substantial Equivalence Summary	The **Arthrex SutureTak Suture Anchors** is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the ***Arthrex SutureTak Suture Anchors*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The submitted tensile testing, fatigue testing, and degradation testing data demonstrates that the performance of the proposed devices meets or exceeds the predicate device for the desired indications. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex SutureTak Suture Anchors*** is substantially equivalent to currently marketed predicate devices.